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10/541,499

07/07/2005

Hisakazu Hojo

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EXAMINER

BEKKER, KELLY JO

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

08/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/541,499 | Applicant(s) HOJO ET AL. | |
| | Examiner Kelly Mahafkey | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/3/05 and 7/7/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "hardly soluble" in claims 1 and 2 is a relative term which renders the claim indefinite. The term "hardly soluble" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to how insoluble a compound must be in order to be considered "hardly soluble". It is unclear as to if "hardly soluble" means "a solubility in water at 20C of not more than 0.1g/100g of water" or if the term "hardly soluble" relates to some other solubility level or range.

Claim 2 recites, "wherein a content of said component (B) is not less than 20% by weight of the total amount of the components (B) and (D)". It is unclear as to what "a content of said component (B)" is. It is unclear as to if the "content of the B component" is the entire component B or some portion of component B.

Claim 4 recites, "condenses phosphates". It is unclear as to what "condenses phosphates" are. It is unclear if applicant intends to recite "condensed phosphates" or as to if the term "condenses phosphate" has some other meaning.

Claims 6 and 7 recite, "sucrose fatty acid esters having an HLB of not less than 8". It is unclear as to what the term "HLB" means. It is unclear as to if the term stands for hydrophilic-lipophilic balance or if the term has some other meaning.

Claim 8 recites, "The food additive composition of claim 1 or 2, wherein a calcium ion concentration (mg/l) satisfies the following requirement (a): (a) 0 greater than or equal to M greater than or equal to 10, wherein M is calcium ion concentration (mg/l) of a food additive composition obtained by adjusting a solid matter concentration of

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calcium to 10% by weight after pulverization and/or dispersion.” It is unclear as to how the range 0-10% is fulfilled by the definition of M, “adjusting a solid matter concentration of calcium to 10%” as the definition appears to only encompass 10% and not the range 0-10%. It is further unclear as to what the “solid matter concentration” is. It is further unclear as to if the “solid matter concentration” is the solid matter in the food additive or the calcium component which is solid or if the term has some other meaning. It is further unclear as to what the solid matter is adjust to; the claim recites, “adjusting a solid matter concentration of calcium to 10% by weight after pulverization...”; it is unclear as to what the solid matter is adjust in reference to; it is unclear as to what “by weight” the solid matter is adjusted by.

Claim 11 recites, “wherein the food is a portion for coffee or black tea”. It is unclear as to how the food is a portion of coffee or black tea. It is unclear as to if the food is coffee or black tea or if the food can be used to make coffee or black tea or if the phrase has some other meaning.

Claim 12 recites, “wherein an ingredient of the portion for coffee or black tea is derived from vegetables”. As stated above, it is unclear as to what a “portion” of the food is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al. (US 6254905 B1) in view of the combination of Grossman (About.com, “Facts About Iron” pages 1-5 <http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html>) and Klahorst (“Calcium, An Important Nutrient” pages 1-5 http://www.ifanca.org/newsletter/2001_05.htm).

Hojo et al. (Hojo) teaches of a food additive composition which contains 100 parts by weight of calcium carbonate, i.e. a hardly water soluble inorganic compound with a solubility in water at 20C of not more than 0.1g/100g of water (Column 3 lines 50-58), 1-60 parts gum arabic (Column 3 lines 50-58) and an additive pullulan, wherein the gum arabic is not less than 20% by weight of the gum arabic and pullulan combined (Column 4 lines 1-4). Thus the gum arabic is at least 20% of the 1-60 parts in the composition or 12 or more parts and the additive is 0-48 parts of the additive composition. Hojo teaches that the inorganic compound has particle size of 0.8um or less (Column 9 lines 25-26). Hojo teaches that the food additive may be used in black tea or coffee (Column 10 line 66 through Column 7 line 3). Hojo teaches that the food additive may contain ferrous gluconate, i.e. a chelating agent as instantly claimed (Column 11 lines 4-8). Hojo teaches that the calcium ion concentration is 10% (Column 10 lines 47-51). Regarding an ingredient in the food as derived from vegetables, as Hojo teaches that the food additive is included in tea and as tea was known to be derived from tea leaves, i.e. known vegetables, Hojo teaches that a portion of the food is derived from vegetables as recited in claim 12.

Hojo is silent to the amount of the ferrous gluconate or chelating agent in the additive composition as recited in claims 1 and 2.

Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11mg per day and for females 8-18 mg per day. (page 3)

Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300 mg per day.

Regarding the amount of ferrous gluconate or chelating agent in the food additive composition, ferrous gluconate was a known food supplement that is a source of iron. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate or chelating agent in the additive composition depending on the amount of iron desired in the final composition. One would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals

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simultaneously; thus as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate, i.e. an iron source per 100 parts of calcium carbonate, i.e. a calcium source.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly Mahafkey whose telephone number is (571) 272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kelly Mahafkey/
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794